

§ 2.308 Special rules governing certain information obtained under the Federal Food, Drug and Cosmetic Act.

(a) *Definitions.* For the purposes of this section:

(1) *Act* means the Federal Food, Drug and Cosmetic Act, as amended, 21 U.S.C. 301 *et seq.*

(2) *Petition* means a petition for the issuance of a regulation establishing a tolerance for a pesticide chemical or exempting the pesticide chemical from the necessity of a tolerance, pursuant to section 408(d) of the Act, 21 U.S.C. 346a(d).

(3) *Petitioner* means a person who has submitted a petition to EPA (or to a predecessor agency).

(b) *Applicability.* (1) This section applies only to business information submitted to EPA (or to an advisory committee established under the Act) by a petitioner, solely in support of a petition which has not been acted on by the publication by EPA of a regulation establishing a tolerance for a pesticide chemical or exempting the pesticide chemical from the necessity of a tolerance, as provided in section 408(d) (2) or (3) of the Act, 21 U.S.C. 346a(d) (2) or (3).

(2) Section 2.307, rather than this section, applies to information described by the first sentence of § 2.307(b) (material incorporated into submissions in order to satisfy the requirements of the Federal Insecticide, Fungicide and Rodenticide Act, as amended), even though such information was originally submitted by a petitioner in support of a petition.

(3) This section does not apply to information gathered by EPA under a proceeding initiated by EPA to establish a tolerance under section 408(e) of the Act, 21 U.S.C. 346a(e).

(c) *Basic rules which apply without change.* Sections 2.201, 2.202, 2.206, 2.207, and 2.210 through 2.215 apply without change to information to which this section applies.

(d) *Effect of submission of information without claim.* Section 2.203 (a) and (b) apply without change to information to which this section applies. Section 2.203(c), however, does not apply to information to which this section applies. A petitioner's failure to assert a

claim when initially submitting a petition shall not constitute a waiver of any claim the petitioner may have.

(e) *Initial action by EPA office.* Section 2.204 applies to information to which this section applies, except that—

(1) Unless the EPA office has on file a written waiver of a petitioner's claim, a petitioner shall be regarded as an affected business, a petition shall be treated as if it were covered by a business confidentiality claim, and an EPA office acting under § 2.204(d) shall determine that the information in the petition is or may be entitled to confidential treatment and shall take action in accordance with § 2.204(d)(1);

(2) In addition to other required provisions of any notice furnished to a petitioner under § 2.204(e), such notice shall state that—

(i) Section 408(f) of the Act, 21 U.S.C. 346a(f), affords absolute confidentiality to information to which this section applies, but after publication by EPA of a regulation establishing a tolerance (or exempting the pesticide chemical from the necessity of a tolerance) neither the Act nor this section affords any protection to the information;

(ii) Information submitted in support of a petition which is also incorporated into a submission in order to satisfy a requirement or condition of the Federal Insecticide, Fungicide and Rodenticide Act, as amended, 7 U.S.C. 136 *et seq.*, is regarded by EPA as being governed, with respect to business confidentiality, by § 2.307 rather than by this section;

(iii) Although it appears that this section may apply to the information at this time, EPA is presently engaged in determining whether for any reason the information is entitled to confidential treatment or will be entitled to such treatment if and when this section no longer applies to the information; and

(iv) Information determined by EPA to be covered by this section will not be disclosed for as long as this section continues to apply, but will be made available to the public thereafter (subject to § 2.210) unless the business furnishes timely comments in response to the notice.

(f) *Final confidentiality determination by EPA legal office.* Section 2.205 applies

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to information to which this section applies, except that—

(1) Notwithstanding § 2.205(i), the General Counsel or his designee, rather than the Regional counsel, shall in all cases make the determinations and take the actions required by § 2.205;

(2) In addition to the circumstances mentioned in § 2.205(f)(1), notice in the form prescribed by § 2.205(f)(2) shall be furnished to each affected business whenever information is found to be entitled to confidential treatment under section 408(f) of the Act but not otherwise entitled to confidential treatment. With respect to such cases, the following sentences shall be substituted for the third sentence of § 2.205(f)(2): “With respect to EPA’s implementation of the determination, the notice shall state that (subject to § 2.210) EPA will make the information available to the public on the thirty-first (31st) calendar day after the business’s receipt of the written notice (or on such later date as is established in lieu thereof under paragraph (f)(3) of this section), unless the EPA legal office has first been notified of the business’s commencement of an action in a Federal court to obtain judicial review of the determination and to obtain preliminary injunctive relief against disclosure; provided, that the information will not be made available to the public for so long as it is entitled to confidential treatment under section 408(f) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 346a(f).”; and

(3) Notwithstanding § 2.205(g), the 31 calendar day period prescribed by § 2.205(f)(2), as modified by paragraph (f)(2) of this section, shall not be shortened without the consent of the business.

(g) [Reserved]

(h) *Substantive criteria for use in confidentiality determinations.* Section 2.208 does not apply to information to which this section applies. Such information shall be determined to be entitled to confidential treatment for so long as this section continues to apply to it.

(i) *Disclosure in special circumstances.* (1) Section 2.209 applies to information to which this section applies. In addition, under Section 408(f) of the Act, 21 U.S.C. 346a(f), EPA is authorized to dis-

close the information to other persons. Such authority under section 408(f) of the Act may be exercised only in accordance with paragraph (i)(2) or (i)(3) of this section.

(2) Information to which this section applies may be disclosed (notwithstanding the fact that it otherwise might be entitled to confidential treatment under this subpart) to a person under contract to EPA to perform work for EPA in connection with the Act, with the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, or regulations which implement either such Act, if the EPA program office managing the contract first determines in writing that such disclosure is necessary in order that the contractor may carry out the work required by the contract. Any such disclosure to a contractor shall be made only in accordance with the procedures and requirements of § 2.301(h)(2) (ii) through (iv).

(3) Information to which this section applies may be disclosed by EPA to an advisory committee in accordance with section 408(d) of the Act, 21 U.S.C. 346a(d).

[41 FR 36902, Sept. 1, 1976, as amended at 43 FR 40005, Sept. 8, 1978]

§ 2.309 Special rules governing certain information obtained under the Marine Protection, Research and Sanctuaries Act of 1972.

(a) *Definitions.* For the purposes of this section:

(1) *Act* means the Marine Protection, Research and Sanctuaries Act of 1972, 33 U.S.C. 1401 *et seq.*

(2) *Permit* means any permit applied for or granted under the Act.

(3) *Application* means an application for a permit.

(b) *Applicability.* This section applies to all information provided to or obtained by EPA as a part of any application or in connection with any permit.

(c) *Basic rules which apply without change.* Sections 2.201 through 2.207 and 2.209 through 2.215 apply without change to information to which this section applies.

(d) *Substantive criteria for use in confidentiality determinations.* Section 2.208 does not apply to information to which